510(k) Summary: UNIFY® Dynamic and ASSURE® Anterior Cervical Plate Systems

Company: Globus Medical Inc.
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
(610) 930-1800

Contact: Christina Kichula
Group Manager, Regulatory Affairs

Date Prepared: November 19, 2013

Device Name: UNIFY® Dynamic Anterior Cervical Plate System
ASSURE® Anterior Cervical Plate System

Classification: Per 21 CFR as follows:
§888.3060: Spinal Intervertebral Body Fixation Orthosis
Product Code: KWQ
Regulatory Class II, Panel Code 87.

Predicate(s): UNIFY® Dynamic Anterior Cervical Plate System (K121049)
ASSURE® Anterior Cervical Plate System (K040721)

Purpose:
The purpose of this submission is to request clearance for additional UNIFY® screws to be used with ASSURE® and UNIFY® plates and use of ASSURE® rigid screws with the UNIFY® plate.

Device Description:
The UNIFY® Dynamic and ASSURE® Anterior Cervical Plate Systems consist of plates and variable or fixed angle screws. The plates attach to the anterior portion of the vertebral body of the cervical spine (C2-C7). The UNIFY® plates allow translation to accommodate bone graft resorption.

The UNIFY® additional implants are manufactured from titanium alloy, as specified in ASTM standards F136, F1295 and F1472.

Indications for Use:
The UNIFY® Dynamic Anterior Cervical Plate System and the ASSURE® Anterior Cervical Plate System are intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors,

deformity (kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

Technological Characteristics:
The technological characteristics of the UNIFY® additional implants are similar to the predicate devices in terms of design, dimensions, intended use, materials, and performance characteristics.

Performance Data:
Mechanical testing (engineering analysis and static cantilever bending and screw push-out) was conducted in accordance with the Guidance for Industry and FDA Staff, Guidance for Spinal System 510(k)s, May 3, 2004. Performance data demonstrate substantial equivalence to the predicate devices.

Basis of Substantial Equivalence:
UNIFY® additional implants are similar to the predicate devices with respect to technical characteristics, material, performance, and intended use. The information provided within this premarket notification supports substantial equivalence to the predicate devices. UNIFY® additional implants perform as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 20, 2014

Globus Medical, Incorporated
Ms. Christina Kichula
Group Manager, Regulatory Affairs
2560 General Armistead Ave.
Audubon, PA 19403 US

Re: K133567
Trade/Device Name: UNIFY® Dynamic Anterior Cervical Plate System,
ASSURE® Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 29, 2014
Received: January 30, 2014

Dear Ms. Kichula:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent D Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133567

Device Name
UNIFY® Dynamic Anterior Cervical Plate System

Indications for Use *(Describe)*
The UNIFY® Dynamic Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD
Division of Orthopedic Devices

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K133567

Device Name
ASSURE® Anterior Cervical Plate System

Indications for Use *(Describe)*
The ASSURE® Anterior Cervical Plate System is intended for anterior screw fixation to the cervical spine C2-C7 for the following indications: degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis or scoliosis), pseudarthrosis, failed previous fusions, spondylolisthesis, and spinal stenosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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